

REMARKS

This Amendment is in response to the final Office action (Paper No. 20090511) mailed on 11 May 2009. Reexamination and reconsideration are respectfully requested.

Listing of The Claims

Pursuant to 37 CFR §121(c), the claim listing, including the text of the claims, will serve to replace all prior versions of the claims, in the application.

Status of The Claims

Upon entry of this Paper, claims 7, 13, and 19 will be pending in this application.

Amendment of The Claims

No claim is amended by this Paper.

Issues raised by Paper No. 20090511

In the final Office action (Paper No. 20090511), the Examiner stated:

- Claims 7,13 and 19 are rejected under 35 U.S.C. §103(a) as being unpatentable over a proposed combination of Cuilleron (FR 2610512 A) modified in view of Hansson et al., U.S. Patent No. 5,588,838.

Applicant respectfully traverses because of the following reasons.

First, as is indicated by a thorough reading of Cuilleron '512, the Examiner's proposed combination fails to teach, or suggest, Applicant's "helical threads." Two observations confirm this omission: first, the perfection of the symmetry in the disposition of the cotyle 1 on both sides of the structures illustrated by Figures 1 and 5, and second, the absence of the adjective "helical" from the

specification of Cuilleron '512. How can Cuilleron '512 be said to teach any peripheral structure except series of space-apart concentric rings if Cuilleron '512 itself does not use the adjective "helical?" The use of "threading" in the English language translation is simply that; "threading" is not synonymous with either "helical" or with "helical threading."

"Helical threads" have been known since the work of Archimedes. Cuilleron '512 knew about "helical threads." Because the implants of Cuilleron '512 are intended for movable anatomical members, such as artificial limbs, the choice of symmetrical radial alignment between the circumferential rings of Cuilleron '512 was deliberate in order to address the peculiarities and necessity of maintaining the implants within their receiving polyethylene cup, free of sympathetic rotation in response to the corresponding rotation of the attached artificial limb. Modifying Cuilleron '512 to incorporate the helically oriented thread 9 of Hansson '838, impermissibly prevents Cuilleron '512 from being used in its intended mode of operation to prevent sympathetic counter-clockwise rotation of the implant in response to rotation of the attached artificial limb.

Accordingly, the combination of Cuilleron '512 and Hansson '838 is impermissible under 35 U.S.C. §103(a). This is persuasive evidence of the absence of obviousness in the pending claims.

Second, as best illustrated by the Table printed below, neither the Examiner's proposed combination nor Cuilleron '512 and Hansson '838, whether taken in various combinations or individually, fail to teach Applicant's,

- "core surrounded by helical threads,
- with the inclined flanks of said threads bearing a continuum of micro-patterns increasing ... ,

- the micro-patterns comprising one or more recesses and protrusions,
and
- the micro-patterns having continuous and repeated arcuate cross-sectional outlines throughout the entire length of the micro-patterns
... .”

Specifically, the threads 9 of Hansson '838 bear neither Applicant's "flanks of ... threads" nor Applicant's "flanks of ... threads bearing a continuum of micro-patterns," and the pitch of the "thread" 9 of Hansson '838 is disclosed as 200 micrometer; consequently, "thread" 9 of Hansson '838 lacks a substrate structure able to support either Applicant's:

(a) "micro-patterns having continuous and repeated arcuate cross-sectional outlines throughout the entire length of the micro-patterns"

or Applicant's,

(b) "micro-patterns having continuous and repeated arcuate cross-sectional outlines throughout the entire length of the micro-patterns, two adjacent said recesses being separated by a distance on an order of 150 μm ."

In short, the administrative record establishes that "thread" 9 of Hansson '838 is unadorned with any sort of micro-patterns as defined by Applicant's claims. These micrometer "differences" may not be ignored, either under the requirement of 35 U.S.C. §103(a) that all "differences" be considered, or under the explicit teachings of Cuilleron '512 and Hansson '838 of the crucial anatomical details necessary for the correct manufacture and use of their respective appliances. The fact that some

aspects of Cuilleron '512 or Hansson '838 may bear some similarity to the definitions given by Applicant's claims is immaterial to the issue of obviousness, particularly where neither reference teaches Applicant's "micro-patterns having continuous and repeated arcuate cross-sectional outlines throughout the entire length of the micro-patterns, two adjacent said recesses being separated by a distance on an order of 150 μm ." In point-of-fact, the evidence introduced into the administrative record demonstrates that Cuilleron '512 fails to suggest either Applicant's (a) "core surrounded by helical threads," or Applicant's (b) "core surrounded by helical threads, with the inclined flanks of said threads bearing a continuum of micro-patterns" and that Hansson '838 lacks Applicant's "micro-patterns having continuous and repeated arcuate cross-sectional outlines throughout the entire length of the micro-patterns."

In short, the finding-of-fact set forth in Paper No. 20090511 that Cuilleron '512 "discloses an implant having a cylindrical cord (Figure 5) **with helical threads (2b)**" is fantasy, unsupported by a thorough reading of Cuilleron '512. As noted in the foregoing paragraphs, two observations confirm this omission in Cuilleron '512: first, the perfection of the symmetry in the disposition of the cotyle 1 on both sides of the structures illustrated by Figures 1 and 5, and second, the absence of the adjective "helical" from the specification of Cuilleron '512. How can Cuilleron '512 be said to teach any peripheral structure except series of space-apart concentric rings if Cuilleron '512 itself does not use the adjective "helical?" The use of "threading" in the English language translation is simply that; "threading" is not synonymous with either "helical" or with "helical threading."

These omissions in the administrative record, together with the Examiner's recognition that Cuilleron '512 "does not explicitly disclose that said micro-patterns have **continuous and**

repeated arcuate cross-sectional outlines,” and the fact that the “threads” 9 of Hansson ‘838 can not simultaneously be said to constitute Applicant’s (a) “helical threads” surrounding a core, or Applicant’s (b) “micro-patterns formed on the flanks of helical threads,” there is no *prima facie* showing of obviousness.

Applicant respectfully submits that neither Hansson ‘838” Figures 1, 2 or 3, nor the Examiner’ proposed combination teach Applicant’s “micro-patterns formed on the flanks of helical threads” because Hansson ‘838 teaches no adorned “flanks.”

Given these deficiencies in the evidence introduced into the administrative record, the evidence does not support the Examiner’s ultimate conclusion of law of obviousness. Withdrawal of this rejection is therefore, respectfully requested.

Third, one of the principal patentable distinctions between the pending claims and the prior art is that the combined prior art fails to teach or suggest Applicant’s claims 7, 13 and 19’s “*two adjacent recesses being separated by a distance on an order of 150 μm* ”. This feature is defined by the pending claims, in terms of:

Claim 7, “two adjacent said recesses being separated by a distance on an order of **150 μm** ”;

Claim 13, “two adjacent said recesses being separated by a distance on an order of **150 μm** ”; and

Claim 19, “the distance between the neighboring micro-patterns being approximately **150 μm** ”.

It is patentably significant that in Paper No. 20090511, the Examiner explicitly admits that Cuilleron ‘512 fails to disclose a specific distance between each micro-pattern.

Paper No. 20090511 refers to Hansson '838 which teaches that the distance between adjacent threads may be approximately 0.2 millimeters (*i.e.*, approximately 200 micrometers (μm)), and alleges that,

“(m)erely providing for similar such spacing (e.g. 150 μm) for the undisclosed spacing of the Cuilleron microthreads in order to promote rapid bone growth into the microthreading would have been obvious to one of ordinary skill in the art.”

Additionally, pages 4 and 5 of Paper No. 20090511 state:

“In the response of October 23, 2008 a declaration under 37 CFR 1.132 by the inventor concluded that the “150 μm micro-pattern provide optimal site for bone ingrowth” (paragraph 11) and provides evidence in the form of test results that show the ingrowth of bone into micro-patterns of 150 μm . The examiner notes that the declaration fails to provide results for any other spacings and as such fails to provide any basis for arguments that the results are unexpected or have any meaningful distinction over the similarly sized spacing of Hansson which is disclosed as promoting bone growth. Moreover, the mere testing of similarly sized spacings in order to find the most optimal spacing is not of no patentable merit, but rather the result of routine testing obvious to the ordinarily skilled artisan.

Applicant further argues in the response of 12/19/2008 the declaration when taken in context with the originally filed specification the claimed spacing is indeed optimal because it also factors in the desire to maintain the largest possible surface contact area between the implant and the bone. The examiner is not persuaded. One desiring to practice the Cuilleron invention would have to determine the spacing of the microthreads 2c on their own accord since Cuilleron is silent on the issue. Hansson et al teaches that for similar microthreads in a bone implant that thread spacing of around 200 μm is desirable because it provides for rapid bone growth. Merely, selecting similar spacing for the Cuilleron microthreading would simply be obvious to the ordinarily skilled artisan as a matter of routine practice.”

Applicant respectfully disagrees with the Examiner's assertion because Applicant's "*150 μ m spacing between adjacent micro-patterns*" is not obtained by a merely routine testing. Rather, Applicant's "*150 μ m spacing*" is carefully selected in order to provide a micro-groove having enough size needed to grow the jaw bone tissue, while maintaining the largest possible surface contact area between the implant and the bone.

The absence of any teaching or suggestions in the evidence introduced into the administrative record of this prosecution history that (a) "*spacing between adjacent micro-patterns*" could be determined by routine testing, or (b) that "*spacing between adjacent micro-patterns*" is a controllable variable that would be a likely candidate for yielding both (i) adequate growth of the jaw bone tissue and (ii) maintain the largest possible surface contact area between the implant and the bond. These omissions from the prosecution history may not be ignored in view of the express command of the U.S. Congress set forth in 35 U.S.C. §103(a) that the "differences" between the subject matter sought to be protected by the pending claims and the prior art be identified, and that those differences be weighed against "the subject matter as a whole" before a conclusion-of-law on obviousness be made.

Specifically, as explained in Applicant's Amendment filed on 23 October 2008, Applicant's original specification explicitly discloses that the number of micro-patterns formed on the thread inclines is preferably to be as great as possible, because as the number of the micro-patterns increased, the contact area of the implant is increased,¹ thereby enhancing the mechanical engaging

¹ Page 6, lines 3-5 of Applicant's original specification reads: "Meanwhile, as **the number of the patterns** is increased, **the contact area** of the implant is also remarkably **increased**, whereas time for machining the patterns is also extended."

force between the implant and the bone.² In order to increase the number of micro-patterns, the spacing between the micro-patterns should be decreased accordingly. On the other hand, Applicant's original specification also explicitly discloses that the size of the micro-patterns should be 100 μm or more because a micro-groove needed to grow the jaw bone tissue has a minimum size of about 100 μm .³ Accordingly, Applicant concludes that the micro-patterns should have a size of 150 μm , in order to provide a micro-groove having enough size needed to grow the jaw bone tissue, while maintaining the largest possible surface contact area between the implant and the bone.

On the other hand, neither one of Cuilleron '512 and Hansson '838 has recognized the need for providing a micro-groove both having (i) enough size needed to grow the jaw bone tissue, while (ii) maintaining the largest possible surface contact area between the implant and the bone. As explicitly admitted by the Examiner, Cuilleron '512 fails to disclose a specific distance between each micro-pattern, and Hansson '838 merely discloses that the distance to the adjacent microthread may be 200 μm . Hansson '838's 200 μm is different from Applicant's 150 μm by more than **30 percent**.

Table I illustrates these deficiencies in the administrative record:

² Page 3, lines 25-30 of Applicant's original specification reads: "The present invention has been made to solve the above problems, and it is an object of the present invention to provide a helical implant, which is formed with a micro-pattern on thread inclines of the helical implant, so that **a contact area and a engaging force between the implant and the jaw bone can be increased**, and so that stress concentration can be restricted, thereby dispersing a physiological load."

³ Page 5, lines 23-25 of Applicant's original specification reads: "... since a micro-groove needed to grow the jaw bone tissue has a minimum size of about 100 Sm, the pattern must be formed to have a size of 100 um or more, preferably 150 m."

Present invention	Cuilleron '512	Hansson '838
a core	an anchoring threading for bone implant	a dental implant having a conically flaring portion 10
surrounded by helical threads		
micro-patterns formed on	micro threads (1f, 2c)	micro-threads 9
the flanks of helical threads		
	formed on the surface of the threading (1c)	formed on the surface of conically flaring portion 10
with the micro-patterns comprising one or more recesses and protrusions, and		

two adjacent said recesses being separated by a distance on an order of 150 μm.	micro threads in the dimension of micrometers	the distance between adjacent micro-threads 9 may be 200 μm.
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It is doubtful, in view of the foregoing noted deficiency in the evidence present in the administrative record, that there is evidence which would permit and inference that one with ordinary skill in the art will combine Hansson '838 and Cuilleron '512 to reach Applicant's "150 μm spacing".

Paper No. 20090511 reached a further conclusion of law about the obviousness *vel non* of the subject matter defined by Applicant's pending claims, namely that,

"the mere testing of similarly sized spacings in order to find the most optimal spacing is not of no patentable merit, but rather the result of **routine testing** obvious to the ordinarily skilled artisan",

and

"Merely, selecting similar spacing for the Cuilleron microthreading would simply be obvious to the ordinarily skilled artisan as a matter of **routine practice**".

This conclusion of law is in conformance with an earlier statement by Thomas Edison,

"Genius is one percent inspiration, ninety-nine percent perspiration."

The laborious routing testing is exactly what Thomas Edison said constitutes an invention. To further buttress the Examiner's conclusions of law, Applicant respectfully submits that in actuality, (a) only by unduly tedious and laborious experimentation would an artisan of ordinary skill in the

art be able to identify which dimension or spacing would be suitable candidates for consideration for use in Applicant's helical implant, and (b) only by further unduly tedious and laborious experimentation would an artisan of ordinary skill in the art be able to obtain,

*"two adjacent recesses being separated by a distance on an order of
150 μm "*

recited by Applicant's claims 7, 13 and 19. This recognition of the necessity for "*routine testing*" which the Examiner has introduced into the administrative record, is the hallmark of non-obviousness under 35 U.S.C. §103(a).

In view of the foregoing amendments and remarks, all claims are deemed to be allowable and this application is believed to be in condition to be passed to issue. Should any questions remain unsolved, the Examiner is respectfully requested to telephone Applicant's undersigned attorney.

No fee is incurred by this Amendment.

Respectfully submitted,

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